## Confidential Attorney-Client Privileged

## Summary Report

Subject:

Additional information on Baxter randomized trial described in ASH 1995 abstract.

Prepared by: Shelly Heimfeld

Date:

March 20, 1997

Listed below is another reference I pulled from a MEDLINE search that gives a small amount of additional information on the Baxter randomized trial described in the ASH 1995 abstract. This was apparently presented at ASCO last year (see attached copy). We may want to see if the ASCO 97 meeting to be held in Denver in May contains any updated information.

Title: Peripheral blood stem cells or isolated CD34+ cells from mobilized peripheral stem cell collection for hematologic rescue of advanced breast cancer patients treated with high-dose chemotherapy (Meeting abstract).

Author: Chabannon C; Viens P; Camerlo J; Gravis G; Faucher C; Novakovitch G; Cornetta K; Lotz JP; Marolleau JP; Rosenfeld C; Chabbert I; Mannoni P; Maraninchi D; Mills B; Oldham F; Blaise D

Address: Institut Paoli-Calmettes, 13009 Marseille, France

Source: Proc Annu Meet Am Soc Clin Oncol; 15:A1013 1996

Abstract: There are indications that high dose chemotherapy with stem cell support improve the outcome of patients with metastatic breast cancer. The availability of biomedical devices able to separate hematopoietic progenitors from other cells result in a lesser reinfusion of contaminating tumor cells. As of October 1995, patients with metastatic breast cancer were included in a multicenter prospective randomized study looking at the safety and efficacy of the ISOLEX 300 SA device to select CD34+ cells from aphereses for clinical transplantation. Peripheral blood (PB) progenitors were mobilized with chemotherapy (in most cases cyclophosphamide 3 g/m2 and doxorubicin 75 mg/m2), and rhG-CSF (Neupogen, Amgen, 300 ug/d or 5 ug/kg/d). Patients underwent apheresis when their PB CD cell counts rose above 20/ul, and were then randomized to receive either unseparated PB cells (target number of cells to be collected =  $2.5 \times 10(6)$  CD34+ cells/kg) or selected CD34+ cells (target number of cells to be collected =  $5 \times 10(6)$  CD cells/kg). Patients who were allocated to the study arm had an additional 1.5 x 10(6) CD34+ cells/kg collected as a backup. Out of the 32 patients who signed the informed consent, 3 were excluded because of intercurrent events and 7 did not achieve adequate mobilization. 11 patients were randomized into each arm. Patients in the study group had on average 1.9 separations. 2 out of 11 patients in the study group were simultaneously infused with the selected cells and the backup, because the numbers of selected CD34+ ceils were 1.01 and 0.43 x 10(6)/leg. An average number of 6.2 x 10(6) CD34+ cells/kg and 3.3 x 10(6) CD34+ cells/kg were cryopreserved and reinfused after completion of high-dose chemotherapy in the 11 control and 9 study patients, respectively (not including the backup collection for the latter). Granulocyte and platelet recovery in the 9 patients were similar in both groups. None of these patients required reinfusion of the backup, and no side effects were observed. The longer follow-up is 335 days. We conclude that selected PB CD34+ cells support adequate hematopoietic recovery in breast cancer patients, although the use of technology may be limited by poor mobilization in a proportion of candidates.

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Listed below is one last reference I found in the MEDLINE search that gives slightly different additional information on the Baxter randomized trial described in the ASH 1995 abstract. This was apparently presented at AACR last year (see attached copy). Again we may want to see if the AACR 97 meeting to be held in San Diego in April contains any updated information.

Title: A randomized study of peripheral blood stem cells or isolated CD34 plus cells for hematologic rescue of advanced breast cancer patients treated with high-dose chemotherapy (Meeting abstract).

Author: Chabannon C; Viens P; Camerlo J; Gravis G; Faucher C; Novakovitch G; Cornetta K; Lotz JP; Marolleau JP; Rosenfeld C; Chabbert I; Mannoni P; Maraninchi D; Mills B; Oldham F; Blaise D

Address: Institute Paoli-Calmettes, Marseille 13273, France

Source: Proc Annu Meet Am Assoc Cancer Res; 37:A1207 1996

Abstract: 42 patients with metastatic breast cancer were included in a multicenter prospective randomized study looking at the use of selected blood CD34+ for clinical transplantation. Peripheral blood (PB) progenitors were mobilized with chemotherapy and rhG-CSF. Patients underwent apheresis when their PB CD34+ cell counts rose above 20/ul, and were then randomized to receive unseparated PB cells or selected CD34+ cells. Three patients were excluded because of unrelated events and 9 did not achieve adequate mobilization. 16 patients were randomized in the study group, and 14 in the control group. Patients in the study group had on average 2 separations. An average number of 7.3 x 10(6) CD34+ cells/kg and 3.2 x 10(6) CD34+ cells/kg were reinfused after completion of high-dose chemotherapy in the control and study patients, respectively. Granulocyte and platelet recovery were similar in both groups. None of these patients required reinfusion of the backup, and no side effects were observed. The longer follow-up is 335 days. We conclude that selected PB CD34+ cells support adequate hematopoietic recovery in breast cancer patients.